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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,241	02/27/2002	Takuya Watanabe	57132 (46342)	2935
21874	7590	09/17/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,241	WATANABE ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 9, 11, 14, and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/7/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed on 06/17/2004 has been entered. Claims 1, 3, 4, 9, 11, and 14 have been amended. Claim 2 has been canceled. Claim 15 has been added. Claims 1 and 3-15 are pending. Claims 1, 3-7, 9, 11, 14, and 15 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

II. Information Disclosure Statement

The Information Disclosure Statement filed on 6/7/2004 has been considered by the Examiner and a fee of \$180 as set forth in §1.17(p) has been charged.

III. Withdrawn Objections and/or Rejections

Applicants' cancellation of claim 2 has made all the rejections of the claim as set forth in the previous office action (Paper No. 1203, 12/17/2003) moot.

The rejection of claims 1, 3, 4, 11, and 14 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, as set forth in the previous office action (Paper No. 1203, 12/17/2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 1, 3-7, 9, and 11 under 35 U.S.C. 112, first paragraph for written description, as set forth in the previous office action (Paper No. 1203, 12/17/2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 1, 3, 5-7, 11, and 14 are rejected under 35 U.S.C. 112, second paragraph, as set forth in the previous office action (Paper No. 1203, 12/17/2003), has been withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 1, 3-7, 9, and 11 under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2003/0148450 A1), as set forth in the previous office action (Paper No. 1203, 12/17/2003), has been withdrawn in view of Applicants' amendment to the claims.

The objection to the claims 9 and 11 as being in improper multiple dependent form has been withdrawn in view of Applicants' amendment to the disclosure.

IV. Claim Rejections under 35 USC § 101

The rejection of claims 1, 3-7, 9, 11, and 14 under 35 U.S.C. §101 for lack of utility, as set forth at pages 3-5 of the previous Office Action (Paper No. 1203, 12/17/2003) is maintained. New claim 15 is also rejected on the same basis. The basis for this rejection is set forth at pages 4-6 of the previous Office Action (Paper No. 1203, 12/17/2003).

At page 10 of the Applicants' response, Applicants argue that Example 3 demonstrates the reactivity of the protein of the present invention with respect to Met-Enkephalin-Arg-Phe amide, whereas the physiological function of the Met-Enkephalin-

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Arg-Phe amide was known to those of skill in the art. Met-Enkephalin-Arg-Phe amide is considered to a lignd for AQ27 because of its reactivity. Applicants further submit that at the time the present application was filed, the AQ27 protein was believed to be associated with circulatory diseases, such as those described on page 55, lines 31-33 of the present specification.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons, as well as for the reasons set forth in the previous office action. First, the instant disclosure does not show that Met-Enkephalin-Arg-Phe amide binds to the protein of SEQ ID NO: 1 (AQ27) and activates the proein. The instant disclosure (Example 3; Fig. 5) merely shows a change in acidification rate with cycle in AQ27-expressing CHO cells exposed to Met-Enkephalin-Arg-Phe amide. There is no disclosure how such a change reflects or correlates with the binding of Met-Enkephalin-Arg-Phe amide to the protein of the present invention and there is no sufficient information regarding the identiftion of Met-Enkephalin-Arg-Phe amide as a ligand of the protein of the presetn invention. Therefore, the instant disclosure does not provide a specific and substantial utility for the claimed invention.

Secondly, the prior art teaches that Met-Enkephalin-Arg-Phe amide acts on different proteins and has diverse physiological effects. The reference of Wong et al. teaches that Met-Enkephalin-Arg-Phe amide increases both blood and pulse pressure when injected into the lateral ventricle of the rat, whereas in the isolated rectum of the clam *Mercenaria mercenaria*, Met-Enkephalin-Arg-Phe amide produces contractures and relax the rectum (right column of page 175). The polypeptide acts on rat brain via

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naloxone-sensitive opiate receptors, whereas in the clam rectum, as well as in other molluscan muscle and myocardial preparations, it acts via receptors insensitive to naloxone (right column of page 178). Even assuming that Met-Enkephalin-Arg-Phe amide were to bind the protein of AQ27, further research would still be required to identify the physiological significance of the protein of the present invention. Moreover, it does not appear that there is a link between a change in acidification rate with cycle in AQ27-expressing CHO cells exposed to Met-Enkephalin-Arg-Phe amide as disclosed in the case here and a specific activity of Met-Enkephalin-Arg-Phe amide taught in the art. Thus, the prior art does not provide a well established utility for the protein of the present invention.

Furthermore, as noted above, Wong et al. teaches that Met-Enkephalin-Arg-Phe amide increases both blood and pulse pressure when injected into the lateral ventricle of the rat. The reference of Wong does not teach that the AQ27 protein was associated with circulatory diseases, such as those described on page 55, lines 31-33 of the present specification.

Accordingly, the instantly claimed invention does not have a specific, substantial utility or a well established utility.

V. Claim Rejections under 35 USC § 112, 1st paragraph, Enablement

Claims 1, 3-7, 9, 11, 14 are rejected under 35 U. S. C. § 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly

would not know how to use the claimed invention. The basis for this rejection is set forth at pages 3-5 of the previous Office Action (Paper No. 1203, 12/17/2003). New claim 15 is also rejected on the same basis.

Applicants' argument about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for the reasons set forth above.

The issue related the scope of enablement of claim 14 as set forth in the previous office action (from the 3rd paragraph of page 5 to top of page 7) still remains. New claim 15 is also rejected on the same basis of scope of enablement. The amended claim 14 and newly added claim 15 are drawn to an isolated DNA which hybridizes to the DNA encoding the protein of SEQ ID NO: 1, without reciting a distinguishing structural feature and a functional limitation. Thus, it would require undue experimentation for one skilled in the art to make and use the broad genus of nucleic acids encompassed by the instant claims.

VI. Claim Rejections under 35 USC § 112, 1st paragraph, Written Description

The rejection of claim 14 under 35 U.S.C. 112, first paragraph for written description, as set forth in the previous office action (Paper No. 1203, 12/17/2003), is maintained. The newly added claim 15 is also rejected on the same basis.

Applicants cite the reference of Wong et al. and argue that the amendment to claim 1 overcomes the present rejection and places claim 1 in condition for allowance.

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Claim ~~3, 5-7, 9, 11,~~ and 14 are dependent on claim 1 and thus the claims fulfill the requirement under 35 U.S.C. 112, first paragraph.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons, as well as for the reasons set forth in the previous office action. First, while the amendment to claim 1 overcome the rejection of claim 1 and its dependent claims 3, 5-7, 9, and 11, it does not overcome the rejection of claim 14. Claims 14 and new claim 15, as written, encompass a genus of nucleic acid that may be structurally and functionally unrelated because the claims do not recite a distinguishing structural feature and a functional limitation. Secondly, claim 3 encompasses a genus of DNAs that encode the protein of SEQ ID NO: 1, not just the DNA of SEQ ID NO: 2. Therefore, claims 14 and 15, which recite an isolated DNA hybridizes to the DNA encoding the protein of SEQ ID NO: 2, are remarkably broad whereas the instant disclosure simply does not provide sufficient description for the claimed broad genus. Finally, the cited reference of Wong et al. does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed nucleic acid molecules as being identical to those instantly claimed.

VII. Claim Rejections under 35 USC § 112, 1st paragraph, New Matter

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 recites a specific highly stringent condition. However, there is no support for the recited condition in the instant disclosure.

Claim 15 recites an isolated DNA which hybridizes to DNA according claim 3 and is either at least 70% identical to the DNA according to claim 3 or at least 70% identical to the complementary strand of the DNA according to claim 3. However, the instant disclosure only provides support for the DNA is at least about 70% identical to the base sequence represented by SEQ ID NO: 2, but not the DNA of claim 3. It is noted that claim 3 encompasses a genus of DNAs that encode the protein of SEQ ID NO: 1, not just the DNA of SEQ ID NO: 2.

VIII. Claim Rejections under 35 USC § 112, 2nd paragraph

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as set forth in the previous office action (Paper No. 1203, 12/17/2003), is maintained.

Applicants argue that the present language of claim 9 fully complies with the definiteness requirement. This is not found to be persuasive for the following reasons. Claim 9 recites the limitation "the reactivity of test substance to the protein or its salt". It is unclear what reactivity of test substance to the ^{protein} Applicants intend to determine. In addition, the steps of the method recited in the claim do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a ligand is identified and correlated to the preamble. It is noted that a method usually has a contacting step, a

measuring step, a selecting step, and a correlation step linking the measuring/selection step to the goal set forth in the preamble.

IX. Claim Rejections under 35 USC § 102 (e)

The rejection of claim 14 under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 2003/0148450 A1), as set forth in the previous office action (Paper No. 1203, 12/17/2003), is maintained. The newly added claim 15 is also rejected on the same basis.

Applicants argue that the cited Chen reference does not contain a description or suggestion of the amino acid sequence represented by SEQ ID NO: 1.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. While the Examiner agrees with Applicants that the reference of Chen does not teach SEQ ID NO: 1, the reference of Chen does teach the nucleic acids of claims 14 and 15. Claim 14 is drawn to an isolated DNA which hybridizes to the DNA according claim 3, whereas claim 15 is drawn to an isolated DNA which hybridizes to the DNA of claim 3 and is at least 70% identical to the DNA of claim 3 or its complementary strand. Chen et al. teach a cDNA that encodes a human orphan G protein coupled receptor with an amino acid sequence being 99.9% identical to SEQ ID NO: 1. This cDNA, by its nature, hybridizes to one of the cDNAs encoding the protein of SEQ ID NO: 1, and is at least 70% identical to the DNA. Thus, the reference of Chen et al. meets the limitations of claims 14 and 15.

X. Claim Objections

The objection to claims 7 under 37 CFR 1.75(c) as being in improper multiple dependent form is maintained because the claim has not been amended to remove the multiple dependency.

Claim 14 is objected to because of an apparent typographic error: "and hybridizes to the DNA according to claim 3" should be deleted.

XI. Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Brenda.Brumback@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Ruixiang Li, Ph.D.
Examiner
September 12, 2004


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